



DELAWARE HEALTH AND SOCIAL SERVICES
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Implementation of QuantiFERON testing

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New FDA Approved Test

- ◆ QuantiFERON (QFT) - blood test for the detection of tuberculosis (TB) infection.
- ◆ Modern alternative to the 100 year old tuberculin skin test (TST).
- ◆ Offers simpler and more accurate, reliable, and convenient TB diagnostic tool.

QFT-TB Gold In-Tube

- ◆ Highly specific & accurate.
- ◆ Positive test - strongly predictive of true infection with *Mycobacterium tuberculosis* (*M. tb*).
- ◆ Aid for diagnosing both active TB disease and latent TB infection (LTBI)-does not differentiate the two.

Benefits of QFT vs TST

Specific Antigen Targets for TB

- ◆ Detects responses to two proteins (early secretory antigenic target-6 [ESAT-6] & culture filtrate protein-10 [CFP-10]).

- ◆ Made by *M. tb.* and are absent from all BCG vaccine preps & environmental nontuberculous mycobacteria (NTM), with the exception of *M. kansasii*, *M. marinum*, and *M. szulgai*.

Cost Savings

- ◆ *Medical staff time* - elimination of a 2nd patient visit for test interpretation .
- ◆ Elimination of false-positive -unnecessary follow-up testing and treatment for LTBI.
- ◆ Eliminate repeat (2 step) testing - used for screening health care workers.
- ◆ Lower cost of maintaining testing compliance in health care facilities, offset the slightly higher reagent cost compared to the TST.

High-risk populations to screen

- ◆ Immunocompromised (e.g. HIV-infected or immunosuppressive meds, including TNF-alpha antagonists, pre-organ transplant patients).
- ◆ Contacts to cases of active TB.
- ◆ Medical risk factors for TB reactivation (e.g. diabetes, chronic renal failure, silicosis, malnutrition, certain cancers).
- ◆ Recent immigrants- from TB endemic areas, regardless of age.

High-risk populations to screen

- ◆ Homeless individuals.
- ◆ Injection drug users.
- ◆ Patients with an abnormal CXR consistent with old or active TB.
- ◆ Residents and employees of high-risk congregate settings (e.g. shelters, nursing homes, jails, substance abuse treatment facilities).

Screen Health Care Workers

- ◆ Routine monitoring practices, including screening following an exposure to *M. tb*.
- ◆ 2005 CDC guidelines introduced QFT as an alternative to the TST for initial and serial screening of health care workers for TB infection.

Test Interpretation

- ◆ ***Like the TST, the QFT is a useful but imperfect diagnostic aide. It should not replace clinical judgment.***

Negative:

- Same interpretation as negative TST.
- No further TB evaluation is needed unless indicated by clinical judgment.

Positive:

- Same interpretation as positive TST.
- Medical evaluation and chest x-ray are needed to determine whether TB **disease** or latent TB infection.
- Note: TB disease still requires culture for identification & susceptibility testing.

Indeterminate:

- Test inconclusive. Repeat QFT or administer TST
- May be due to laboratory problems or patient anergy (immune compromised)
- If two different specimens from a patient yield indeterminate results, do not repeat for that person.

Importance of Collection

- ◆ Correct collection of blood specimens is *absolutely critical* in the QFT In-tube test.
- ◆ Differs from other lab tests drawn off-site - testing process begins *IMMEDIATELY* upon the correct volume of blood entering the tube.

QFT Collection

- ◆ Collect tubes in order (Nil, Antigen, Mitogen) (Green/Red/Purple=GRP="Grape").
- ◆ Tubes are calibrated to accept 1 mL of whole blood.
- ◆ Shake tubes vigorously for 5 seconds, must see "FOAMING".

Incubation & Transport

- ◆ Incubate in 37°C incubator for 16-24 hours (within 16 hours of collection).
- ◆ Following incubation, specimens should be stored and transported at 2-27°C (Frig or RT) within 3 days. Collection Mon-Thurs for DPHL.
- ◆ After centrifugation, samples stable for 28 days at 4°C.

References

- ◆ Guidelines for Using QuantiFERON-TB Gold Test for Detecting *Mycobacterium tuberculosis* Infection, United States. MMWR 2005;54 -RR-15:49-55.
- ◆ Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health Care Settings, 2005. MMWR 2005;54 RR-17:1-141.
- ◆ Richeldi L. An update on the diagnosis of tuberculosis infection. Am J Respir Crit Care Med. 2006;174:736-42.
- ◆ Cellestis, Ltd., Carnegie, Australia. www.cellestis.com
- ◆ NYC, Bureau of TB Control, QFT-G Provider Fact Sheet February 2007